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## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA Alexandria Division

TRIANTAFYLLOS TAFAS,	
Plaintiff,	)
v.	) Case No. 1:07cv846 (JCC/TRJ)
JON W. DUDAS, et al.,	)
Defendants.	) ) )
CONS	SOLIDATED WITH
SMITHKLINE BEECHAM	
CORPORATION, et al.,	Ó
Plaintiff,	)
v.	) Case No. 1:07cv1008 (JCC/TRJ)
JON W. DUDAS, et al.,	)
Defendants.	)

## DECLARATION OF MEL BILLINGSLEY IN SUPPORT OF AMICUS CURIAE THE PENNSYLVANIA GREENHOUSES' BRIEF IN SUPPORT OF PLAINTIFFS' ANTICIPATED MOTIONS FOR SUMMARY JUDGMENT

- I, Mel Billingsley, do hereby state the following:
- 1. I am President and Chief Executive Officer of the Life Sciences Greenhouse of Central Pennsylvania ("LSGPA").

- 2. LSGPA is principally a state-funded enterprise. LSGPA, one of three Pennsylvania Greenhouses, was initially funded by monies received from the Commonwealth of Pennsylvania's share of The Tobacco Settlement Act of 2001. LSGPA has received additional monies from the Commonwealth of Pennsylvania, as well as from returns on its investments.
- 3. LSGPA seeks to improve human health and provide a strong base for regional business investments. The mission of LSGPA is to advance the life sciences and to improve the lives of Pennsylvanians through improved healthcare and enhanced economic opportunity.

  Funded with monies received from The Tobacco Settlement Act of 2001, LSGPA partners with a range of institutions, including local research universities, colleges, medical centers, economic development agencies and companies both small and large, to identify needs and opportunities.

  LSGPA then works to help transfer technologies, to develop new companies, to provide support for existing companies, particularly those seeking to expand or relocate, and to ensure that the infrastructure necessary to support a thriving life sciences industry keeps pace with development.
- 4. LSGPA's investment philosophy is consistent with its ambitions to improve human health and provide a strong base for regional business investments. A typical investment of up to \$1 million is founded on a novel life sciences technology with strong market potential that is supported by a skilled management team and a sound financial plan, complemented by a robust intellectual property portfolio. Typical investments include companies that have demonstrated a long-term commitment to Pennsylvania and a high likelihood of raising matching funds or follow-on funding.
- 5. LSGPA has invested \$9 million in seed and pre-seed stage capital, nearly \$3.7 million in small businesses and university-based initiatives for the refinement of cutting edge

technologies, and \$3.4 million dollars committed to relocation efforts and the build-out of incubators with wet lab space. Representative investments include Acies, Inc., which acquires, develops, and markets products for burns and wound care; Chaperone Technologies, Inc., which seeks to discover new antibacterial medicines; Hanson Technologies, Inc., which is developing integrated biological and chemical sensors; and NanoHorizons, Inc., which manufacturers and develops nanoparticles and nanofilms—a promising technology for the advancement of biotechnology. Other activities and information on companies associated with LSGPA are described in Appendix A attached hereto.

- 6. Patent protection is vital to the companies in which LSGPA invests. Each stage of funding by LSGPA in an early-stage life science companies depends, in large part, on the company's ability to obtain patents on the technologies and products that it has developed.
- 7. In my experience, the ability to obtain clear and comprehensive patent protection is a key element in attracting necessary additional capital investment, as well as corporate partners necessary to commence the costly research and development of life science inventions. Sustaining an adequate, ever-increasing level of financing and partnering during continued research and development, clinical investigations, regulatory approval, and commercialization of a life science product depends upon a funded company's ability to obtain comprehensive patent protection. The ability of an early-stage life science company to obtain capital is therefore directly tied to its intellectual property assets and particularly to its patent portfolio.
- 8. I am familiar with the final rules published by the United States Patent and Trademark Office ("PTO") on August 21, 2007 as Changes to Practice for Continued

Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716 (Aug. 21, 2007) (hereinafter "Final Rules") (to be codified at 37 C.F.R. pt. 1).

- 9. LSGPA opposes implementation of the Final Rules because, among other things, the Final Rules will shift the burden of examination onto patent applicants by requiring the preparation of an "Examination Support Document," which will lead to an increase in legal fees, as well as unfairly restricted opportunities for obtaining patent protection.
- 10. In my experience, life science product development is extremely expensive. Early state life science companies will be adversely affected if they are forced to allocate additional funds toward patent prosecution as a result of the proposed changes to the PTO's rules.
- 11. If a life science company were to lose its basic patent coverage or be forced to give up the protections afforded by current continuation application practice, it is possible that LSGPA and other investors may decline the next stage or round of investment because of the loss of patent exclusivity and the resulting economic disincentive to develop and commercialize new products.
- 12. In my experience, early-stage life science companies rely heavily on the certainty of the patent system to attempt to secure market exclusivity on any inventions so as to enable those companies and their investors to recover their investments. LSGPA and its funded companies rely heavily on patent protection, as well as the current, established PTO rules of practice, to obtain adequate coverage for inventions and to attract the necessary financial investment to research, develop, and commercialize life science products.

13. In my experience, many early-stage life science companies' sole assets are their intellectual property. They typically do not own office space, lab space, computers, laboratory equipment, and the like—such items are often rented or leased. They also typically do not have any substantial revenue or accounts receivable. Accordingly, the valuation of such life science companies is based almost entirely on the quality of their intellectual property portfolios, especially their patents, pending patent applications, and inventions.

14. I declare under penalty of perjury that to the best of my knowledge the foregoing is true and correct.

12-21-07

Mel Billingsley, Ph.D.

President and Chief Executive Officer

The Life Sciences Greenhouse

of Central Pennsylvania

## **APPENDIX A**